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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,701	01/11/2002	John M. Swoyer	P-9869.00	9808
27581	7590	07/02/2004		EXAMINER
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604				MACHUGA, JOSEPH S
			ART UNIT	PAPER NUMBER
				3762

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	J
	10/045,701	SWOYER ET AL.	
	Examiner	Art Unit	
	Joseph S. Machuga	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-25,30-39 and 41-79 is/are rejected.
- 7) Claim(s) 26-29,40 and 80-83 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____ .

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 21, which both recite details of the embodiment having the hook, depend upon claim 11 which is directed to the embodiment having the helix. This makes the claims indefinite. For the sake of expediting examination these claims will be considered to be dependent upon claim 12.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 1-7, 23-25, 30-37, 52-56 and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois #5836994 in view of Rockland et al #4010758 and Bourgeois et al #5716392.

Bourgeois #994 discloses a gastrointestinal implant having a stimulator 3, lead body, electrode leads, connector and electrode head 25. The electrode head is coated with an antibacterial agent and extends into the muscularis externa region of the stomach. Not disclosed by this reference is the specifics of the electrode assembly.

Rockland et al disclose an electrode assembly for use with cardiac patients. The electrode includes the recited lead body, electrode head, first lead connector, first lead conductor and the active helical fixation mechanism. The helical design of the electrode insures a secure coupling to the organ.

Bourgeois et al #392 teaches that an electrode assembly for use with cardiac patients can also be used for implantation in the stomach (column 7, lines 23-37.)

It would have been obvious to one of ordinary skill in the art to use a screw type electrode assembly such as that disclosed by Rockland et al in place of the electrode disclosed by Bourgeois #994 given Rockland et al's teaching that this type of electrode is old and well known in the art and provides a secure coupling and in view of Bourgeois teaching that cardiac electrode assemblies have use as gastrointestinal implants. To extend the electrode into the muscularis externa would have been obvious given Bourgeois #994 that teaches placing an electrode in this region. The dimensions recited in the claims are considered obvious since Bourgeois #994 teaches extending the electrode into the muscularis externa. To add an antibacterial coating to the screw is

considered obvious given Bourgeois's teaching of this to reduce inflammation and complications. The method claims are considered obvious in view of the proposed combination since the steps of accessing, perforating, advancing and connecting would have to take place to install the device.

5. Claim 1-5, 7-9, 11, 20, 23, 25, 30-39, 52-60, 62-64 and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois #5836994 in view if Dutcher et al #4357946 and Bourgeois et al #5716392.

Bourgeois #994 discloses a gastrointestinal implant having a stimulator 3, lead body, electrode leads, connector and electrode head 25. The electrode head is coated with an antibacterial agent and extends into the muscularis externa region of the stomach. Not disclosed by this reference is the specifics of the electrode assembly.

Dutcher et al disclose an electrode assembly for use with cardiac patients. The electrode includes the recited lead body, electrode head first lead connector, first lead conductor, plate 34 and the active helical fixation mechanism. The helical design of the electrode insures a secure coupling to the organ.

Bourgeois et al #392 teaches that an electrode assembly for use with cardiac patients can also be used for implantation in the stomach (column 7, lines 23-37.)

It would have been obvious to one of ordinary skill in the art to use a screw type electrode assembly such as that disclosed by Dutcher et al in place of the electrode disclosed by Bourgeois #994 given Dutcher et al's teaching that this type of electrode is old and well known in the art and provides a secure coupling and in view of Bourgeois teaching that cardiac electrode assemblies have use as gastrointestinal implants. To extend the electrode into the muscularis externa would have been obvious given Bourgeois #994 that teaches placing an electrode in this region. The dimensions recited in the claims are considered obvious since Bourgeois #994 teaches extending the electrode into the muscularis externa. To add an antibacterial coating to the screw is considered obvious given Bourgeois's teaching of this to reduce inflammation and complications. The method claims are considered obvious in view of the proposed combination since the steps of accessing, perforating, advancing and connecting would have to take place to install the device.

6. Claims 6, 24, 54, 61 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois #5836994 in view of Dutcher et al #4357946 and Bourgeois et al #5716392 as applied to claims 1-5, 7-9, 11, 20, 23, 25, 30-39, 52, 53, 55-60, 62-64 and 77-79 above, and further in view of Rockland et al #4010758.

Rockland et al disclose an electrode assembly for use with cardiac patients. The electrode includes the recited lead body, electrode head first lead connector, first lead

conductor and the active helical fixation mechanism. The helical portion includes a layer of insulation over the first portion of the screw. The helical design of the electrode insures a secure coupling to the organ.

To add a layer of insulation to a portion of the electrode in the assembly of the proposed combination would have been obvious given Rockland's et al's teaching that it is old and well known to covers portions not designed to deliver current to body tissue.

7. Claims 1, 12-22, 23-25, 30-31, 41-51, 52-56 and 67-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois #5836994 in view of Strokes #4313448 and Bourgeois et al #5716392.

Bourgeois #994 discloses a gastrointestinal implant having a stimulator 3, lead body, electrode leads, connector and electrode head 25. The electrode head is coated with an antibacterial agent and extends into the muscularis externa region of the stomach. Not disclosed by this reference is the specifics of the electrode assembly.

Strokes disclose an electrode assembly for use with cardiac patients. The electrode includes the recited lead body; electrode head first lead connector, first lead conductor, plate 18 and the hook 12. The hook design of the electrode insures a secure coupling to the organ.

Bourgeois et al #392 teaches that an electrode assembly for use with cardiac patients can also be used for implantation in the stomach (column 7, lines 23-37.)

It would have been obvious to one of ordinary skill in the art to use a hook type electrode assembly such as that disclosed by Strokes in place of the electrode disclosed by Bourgeois #994 given Strokes teaching that this type of electrode is old and well known in the art and provides a secure coupling and in view of Bourgeois teaching that cardiac electrode assemblies have use as gastrointestinal implants. To extend the electrode into the muscularis externa would have been obvious given Bourgeois #994 that teaches placing an electrode in this region. The dimensions recited in the claims are considered obvious since Bourgeois #994 teaches extending the electrode into the muscularis externa. To add an antibacterial coating to the hook is considered obvious given Bourgeois's teaching of this to reduce inflammation and complications. The method claims are considered obvious in view of the proposed combination since the steps of accessing, perforating, advancing and connecting would have to take place to install the device.

8. Claims 10, 11, 56, 57, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois #5836994 in view if Dutcher et al #5143090 and Bourgeois et al #5716392.

Bourgeois #994 discloses a gastrointestinal implant having a stimulator 3, lead body, electrode leads, connector and electrode head 25. The electrode head is coated with an antibacterial agent and extends into the muscularis externa region of the stomach. Not disclosed by this reference is the specifics of the electrode assembly.

Dutcher et al disclose an electrode assembly for use with cardiac patients. The electrode includes the recited lead body, electrode head first lead connector, first lead conductor, active helical fixation mechanism and a second electrode (fig 14). The helical design of the electrode insures a secure coupling to the organ.

Bourgeois et al #392 teaches that an electrode assembly for use with cardiac patients can also be used for implantation in the stomach (column 7, lines 23-37.)

It would have been obvious to one of ordinary skill in the art to use a screw type electrode assembly such as that disclosed by Dutcher et al in place of the electrode disclosed by Bourgeois #994 given Dutcher et al's teaching that this type of electrode is old and well known in the art and provides a secure coupling and in view of Bourgeois teaching that cardiac electrode assemblies have use as gastrointestinal implants. To extend the electrode into the muscularis externa would have been obvious given Bourgeois #994 that teaches placing an electrode in this region. The dimensions recited in the claims are considered obvious since Bourgeois #994 teaches extending

the electrode into the muscularis externa. To add an antibacterial coating to the screw is considered obvious given Bourgeois's teaching of this to reduce inflammation and complications. The method claims are considered obvious in view of the proposed combination since the steps of accessing, perforating, advancing and connecting would have to take place to install the device.

***Allowable Subject Matter***

9. Claims 26-29, 40 and 80-83 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
  
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Joseph S. Machuga*  
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Examiner  
Art Unit 3762

*Angela D. Sykes*

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